

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Assessment of a topical nano formulation of tretinoin effect in the treatment of Hand-foot syndrome as a side effect of chemotherapeutic agents (Capecitabine, Fluorouracil, Doxorubicin, Docetaxel)

#### Protocol summary

##### Summary

The aim of this study is to suggest a proper topical nano formulation of tretinoin to improve Hand-foot syndrome symptoms in patients who received chemotherapy agents like: Capecitabine, Fluorouracil and Docetaxel. 30 cancer patients between 30-80 years old of both sexes with hand-foot syndrome induced by chemotherapy agents are recruited. Written informed consent was achieved from all the patients. Patients are excluded from the investigation in the case of skin infection, sensitivity to our formulation and unwillingness to take apart in the study. This study was designed as a double-blind, placebo-controlled, parallel and randomized clinical trial. Patients were entered in two groups randomly. Group A were patients who applied a thin layer of topical drug on their hands and feet once or twice daily. Group B were patients who received topical placebo with similar regimen. We helped Common Terminology Criteria for Adverse Events (CTCAE) for grading syndrome based on the severity of symptoms. The beginning and the ending day of study, the severity of lesions are checked, photographed and questionnaire is completed and changes are investigated, also each patient was followed every 14 days. The treatment period varied from one to three months based on the patient's response.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201707163106N33**

Registration date: **2017-10-10, 1396/07/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-10, 1396/07/18

##### Registrant information

###### Name

Farshad Hashemian

###### Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

###### Country

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##### Recruitment status

###### Recruitment complete

##### Funding source

by student

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of a topical nano formulation of tretinoin effect in the treatment of Hand-foot syndrome as a side effect of chemotherapeutic agents (Capecitabine, Fluorouracil, Doxorubicin, Docetaxel)

##### Public title

Assessment of a topical retinoid effect in the treatment

of a cutaneous side effect of chemotherapeutic agents

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: Patients with hand-foot syndrome; Patients who 30 to 80 years old. Exclusion criteria: Skin infections; Skin cancer; Sensitivity to compounds of formula; Patient dissatisfaction

#### **Age**

From **30 years** old to **80 years** old

#### **Gender**

Both

#### **Phase**

1-2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **30**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### 1

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Islamic Azad University Of  
Pharmaceutical Sciences Branch

###### **Street address**

Yakhchal Avenue, Qolhak, Dotor Shariati Avenue,  
Tehran

###### **City**

Tehran

###### **Postal code**

##### **Approval date**

2016-05-17, 1395/02/28

##### **Ethics committee reference number**

IR.IAU.PS.REC.1395.10

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

hand-foot syndrome

##### **ICD-10 code**

L27.1

#### **ICD-10 code description**

localized skin eruption due to drugs and medicaments

### **Primary outcomes**

#### 1

##### **Description**

Severity of hand-foot syndrome

##### **Timepoint**

Beginning of the study, every 14 days, End of the study

##### **Method of measurement**

Common Terminology Criteria for Adverse Events

### **Secondary outcomes**

#### 1

##### **Description**

Skin Sensitivity

##### **Timepoint**

Beginning of the study, every 14 days, End of the study

##### **Method of measurement**

Observational

### **Intervention groups**

#### 1

##### **Description**

The topical nano-tretinoin will be administrated to hands and feet of patients once or twice daily for 1 to 3 months Based on patients' response.

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

The topical placebo will be administrated to hands and feet of patients once or twice daily for 1 to 3 months Based on patients' response.

##### **Category**

Placebo

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Booali haspital

###### **Full name of responsible person**

###### **Street address**

###### **City**

Tehran

#### 2

##### **Recruitment center**

###### **Name of recruitment center**

Firoozgar hospital  
**Full name of responsible person**  
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**3**

**Recruitment center**  
**Name of recruitment center**  
Rasoole Akram hospital  
**Full name of responsible person**  
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**City**  
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## Sponsors / Funding sources

**1**

**Sponsor**  
**Name of organization / entity**  
Pharmaceutical Sciences branch, Islamic Azad University(a part of hanieh pourmousavi's PharmD thesis)  
**Full name of responsible person**  
Dr.Seyd Jalaledin Hosseini Ghoncheh  
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Islamic Azad University Of Pharmaceutical Sciences Branch, Yakhchal avenue, Dotor Shariati avenue, Tehran  
**City**  
tehran  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Pharmaceutical Sciences branch, Islamic Azad University(a part of hanieh pourmousavi's PharmD thesis)  
**Proportion provided by this source**  
100  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

**Contact**  
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**Position**

student of pharmacy  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**

*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*